

FEB 17 2006

VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, California 92121
Telephone: (858) 909-1868
Fax: (858) 909-2068

B. Device Name

| | |
|----------------------------|---|
| Trade or Proprietary Name: | <i>NuVasive SmartPlate Gradient Plus System</i> |
| Common or Usual Name: | Cervical Plate and Screw System |
| Classification Name: | Spinal Intervertebral Body Fixation Orthosis |
| Device Class: | Class II |
| Classification: | §888.3060 |
| Product Code: | KWQ |

C. Predicate Devices

The subject *SmartPlate Gradient Plus System* is substantially equivalent to the *SmartPlate Gradient CLP System* currently distributed commercially in the U.S. by NuVasive.

D. Device Description

The NuVasive SmartPlate Gradient Plus System consists of a variety of plates, screws, and screw-retaining covers designed to provide stabilization as an adjunct to cervical fusion.

E. Intended Use

The NuVasive SmartPlate Gradient Plus System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive SmartPlate Gradient Plus System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

NuVasive, Inc
c/o Ms. Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance
4545 Towne Centre Court
San Diego, California 92121

Re: K053581
Trade/Device Name: NuVasive SmartPlate Gradient Plus System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 22, 2005
Received: December 27, 2005

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

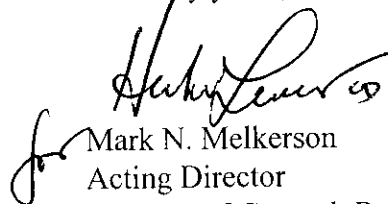
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line. To the left of the signature, there is a small, stylized handwritten mark that looks like "for".

Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1/1

Indications for Use

510(k) Number (if known): K653531

Device Name: SmartPlate® Gradient™ Plus System

Indications For Use:

The NuVasive SmartPlate Gradient Plus System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive SmartPlate Gradient Plus System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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